# FOREIGN LABORATORY CLIA CERTIFICATION PROCESS

The following provides basic information about CLIA for foreign laboratories seeking CLIA certification. This includes instructions for foreign laboratories on obtaining and completing required forms and other important information. Additional information is also found on the CLIA website at www.cms.hhs.gov/clia.

The New York Regional Office (NYRO) of the Centers for Medicare & Medicaid Services (CMS) of the U.S. Department of Health and Human Services (HHS) is the primary contact for foreign laboratories seeking CLIA certification. The NYRO address is 26 Federal Plaza, Room 37-130, New York, NY, USA 10278. Contacts are:


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## Applicability of CLIA to Foreign Laboratories

42 CFR 493.2 defines a laboratory as a facility that examines materials "derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings."

For CLIA purposes, a foreign laboratory is a facility outside the U.S. or its territories that performs laboratory tests for the assessment of the health of human beings when such tests are referred by, and the results are returned to, a facility or authorized person in the U.S. or its territories.

Any testing of materials from human specimens collected in the United States and its territories is subject to CLIA regulations. If specimens are transported outside of the United States and its territories for testing by foreign laboratories, then these laboratories are also subject to the CLIA regulations.

CLIA regulations are applicable only to those tests that are performed on human specimens collected from the United States and its territories. A laboratory may have an array of different tests but performs only molecular genetics testing on specimens from the United States. In this case, only those specimens tested for molecular genetics are subject to CLIA regulations.

Foreign laboratories may also be subject to additional State laboratory requirements. The CLIA website has a listing of contacts in all State Agencies.

## CLIA Certification and or Accreditation

Foreign laboratories may seek CLIA certification through CMS-approved accreditation organizations.

Foreign laboratories that do not seek CLIA certification through CMS-approved accreditation organizations should apply for the level of CLIA certification appropriate for the testing being performed.

## CMS Forms

***CLIA Registration Form, CMS-116: CLIA Application for Certification***

A foreign laboratory seeking accreditation or certification must first register via the form, CMS-116, CLIA Application for Certification. Instructions for completing this form are on the CMS CLIA website. Foreign laboratories are reminded to include only the test volume of specimens coming from the United States and it territories.

The signed application form must be sent to the CMS NYRO address noted above. Be sure to specify **Attention: CLIA Program.** For efficient communication, include the name and, if available, e-mail address of an English-speaking contact.

The CMS-116 may also be sent by email to Halda Greenidge or by faxing to her attention at 212-264-6814.

***CMS-209: Laboratory Personnel Report (CLIA)***

This form is available at http://www.cms.hhs.gov/cmsforms/downloads/CMS209.pdf and must be signed by the laboratory director. Instructions are on the form. To complete the form, the laboratory must identify the appropriate categorization of its test system(s). Refer to the FDA test complexity database for the categorization of a test system.

A test system categorized as moderate complexity is subject to the personnel requirements at 42 CFR 493.1403 through 1425. A test system categorized as high complexity is subject to the personnel requirements at 42 CFR 493.1441 through 1495. A laboratory performing moderate complexity testing requires a Laboratory Director, Clinical Consultant, Technical Consultant, and Testing personnel. A laboratory performing high complexity testing requires a Laboratory Director, Clinical Consultant, Technical Supervisor, General Supervisor, and Testing personnel. In both instances,

laboratory personnel may assume multiple responsibilities. For example, a laboratory director may perform the duties of a clinical consultant and a technical supervisor may also perform the responsibilities of the general supervisor.

Specify only those individuals performing testing and reporting test results. Laboratory personnel performing only specimen preparation and accessioning are not considered testing personnel.

***CMS-1557: Survey Report Form (CLIA)***
This form is available at http://www.cms.hhs.gov/cmsforms/downloads/cms1557.pdf . Note that some sections, such as State/County and Region codes, under the General Information may not be applicable to foreign laboratories.

Under the Personnel section, consideration must be given on the complexity level of the laboratory's test system (moderate or high complexity). Indicate the number of qualified personnel for each chosen category.

Under the Specialties/Subspecialties section, select the appropriate CLIA specialty/subspecialty based on the test system(s) used. Provide estimates of the yearly test volume for each specimen collected from the United States and its territories.